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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,056	01/25/2006	Bruce E. Reidenberg	02755/100I553-US1	2084

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
09/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,056	REIDENBERG ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21 are pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 7, 12-21, drawn to a method of treating postoperative pain in a patient in need of such treatment, which method comprises administering to said patient a buprenorphine-containing transdermal dosage form 12-96 hours prior to surgery.

Group II, claim(s) 1, 3, 7-21, drawn to method of treating postoperative pain in a patient in need of such treatment, which method comprises administering to said patient a buprenorphine-containing transdermal dosage form prior to surgery and administration of a second buprenorphine-containing transdermal dosage form for a second dosing period post-operatively, wherein said second dosage form comprises the same dosage of buprenorphine as, or a greater dosage of buprenorphine than, said first dosage form.

Group III, claim(s) 1, 4, 7, 12-21, drawn to a method of treating postoperative pain in a patient in need of such treatment, which method comprises administering to said patient a buprenorphine-containing transdermal dosage form prior to surgery and further comprising extended subsequent dosing periods with subsequent dosage forms for a given time period as needed by the patient to achieve desired analgesia.

Group IV, claim(s) 1, 5-7, 12-21, drawn to a method of treating postoperative pain in a patient in need of such treatment, which method comprises administering to said patient a buprenorphine-containing transdermal dosage form prior to surgery and further comprises a rapid dose escalation of buprenorphine patches to achieve the desired preoperative dosage level, wherein the method involves: (a) administering to the patient

a first buprenorpnine-containing transdermal dosage form for a first dosing period that is no longer than 5 days; (b) administering to the patient a second buprenorphine-containing transdermal dosage form for a second dosing period that is no longer than 5 days, wherein the second dosage form comprises the same dosage of buprenorphine as, or a greater dosage of buprenorphine than, the first dosage form; and (c) administering to the patient a third buprenorphine-containing transdermal dosage form for a third dosing period, wherein the third dosage form comprises a greater dosage of buprenorphine than the second dosage form, and the third dosage form is the desired dosage level for the postoperative pain control. The method initiated 4-10 days prior to surgery.

2. The inventions listed as Groups I, II, III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I does not require second dosage form of buprenorphine after the pre-operative transdermal patch that is applied12-96 hours prior to surgery. To the contrary, inventions of Group II, III and IV all require further administration of at least second dosage form of buprenorphine. Another distinction of Group II is that this group requires second transdermal patch. Group III is distinct in that Group III does not require the second or subsequent dose to be transdermal patches. Group IV requires three transdermal dosage forms and requires initiation of treatment 4-10 days prior to surgery and none of the other groups require such period.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) Arthroscopic surgery,

b) Excision of a mass,

c) Hernia repair,

d) Spinal fusion,

e) Intrathoracic coarctation repair, or

f) trans-abdominal hysterectomy.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Species a: claims 12 and 13
Species b: claims 12 and 14
Species c: claims 12 and 15
Species d: claims 12 and 16
Species e: claims 17 and 19
Species f: claims 19 and 20

The following claim(s) are generic: claim 1.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each surgery may require different time and dose for pre-operative administration of buprenorphine as well as post operative period and dose of buprenorphine administration. Further, the simple surgery may require local anesthesia and major intrathoracic and pelvic surgeries may require general anesthesia and consequently different doses of pre and post operative pain relief.

6. Because the above restriction/election requirement is complex, a telephone call to the applicant's agent to request oral election was not made. See MPEP, Sec.812.01.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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